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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,427	04/15/2005	Toshiyuki Miyata	0020-5363PUS1	2681
2292 7590 09/17/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER KIM, ALEXANDER D				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
09/17/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/531,427

Applicant(s)

MIYATA ET AL.

Examiner

ALEXANDER D. KIM

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,9,11-18 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 15-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,11,13-14, 17-18,20,21 and 23-28 is/are rejected.
- 7) ☒ Claim(s) 9,12,22 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on 01/15/2009), Applicants filed a response and amendment received on 06/04/2009. Claims 1-4, 7-8, 10, and 19 are cancelled; Claims 5-6, 9, 11-17, 20-24 are amended; and Claims 25-29 are newly added.

Claims 5-6, 9, 11-18 and 20-29 are pending in the instant Office action. Claims 15-16 are withdrawn as non-elected inventions.

Claims 5-6, 9, 11-14, 17-18 and 20-29 will be examined herein.

Claim Objections

2. Claims 5-6, 9, 11-14, 17-18 and 20-29 are objected to because of the following informalities:

- (a) Claims 5 and 6 (Claims 17-18 and 25-28 dependent therefrom) recite "covalently attached tag sequence for...(ADAMTS-13)". In the interest of improving claim format, the Examiner suggests amending claims 5 and 6 to recite ---An isolated substrate polypeptide for a disintegrin-like and metalloprotease with Thrombospondin type-1 motif, 13 (ADAMTS13) and an optionally included covalently attached heterologous tag, wherein the isolated substrate polypeptide begins at amino acid...---.
- (b) Claim 9 (Claims 11-14, 17, 20-24 and 29 dependent therefrom) recites "said polypeptide has a cleavage site between the 1605th Tyr and 1606th Met of SEQ

ID NO: 1 for ADAMTS-13" which reads on a substrate polypeptide having a cleavage site inserted between the 1605th Tyr and 1606th Met of SEQ ID NO: 1 wherein the insertion is within the less than 10% variation in an amino acid sequence of the peptide encompassed by the claim. To improve claim form, the examiner suggests changing said recitation to ---wherein said polypeptide has 1605th Tyr and 1606th Met of SEQ ID NO: 1; and the 1605th Tyr and 1606th Met of SEQ ID NO: 1 is a cleavage site for ADAMTS-13--- and place the amendment at the end of claim 9.

(c) Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 from which claim 11 depends is limited to an isolated polypeptide as encompassed by the claims. Claim 11 recites "further having a tag sequence..." and thus does not further limit the polypeptide of claim 9. In order to correct claim dependency, it is suggested that claim 11 be amended to recite, *e.g.*, ---A polypeptide comprising the isolated polypeptide of claim 9 and a tag sequence at the N-terminal and/or at the C-terminal of the polypeptide of claim 9---.

(d) Claim 12 is objected to in the recitation of "selected the group consisting of" and in order to improve claim form, it is suggested that the noted phrase be amended to recite, *e.g.*, "selected from the group consisting of".

Withdrawn-Claim Rejections - 35 USC § 112

3. The previous new matter rejection of Claim 6 under 35 U.S.C. 112, first paragraph, is withdrawn by virtue of applicants' amendment (i.e., reciting "covalently attached tag").
4. The previous written description rejection of Claims 9, 11-14, 17 and 20-24 under 35 U.S.C. § 112, first paragraph, is withdrawn by virtue of applicants' amendment.
5. The previous rejection of Claims 9, 11-14, 17 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn by virtue of applicants' amendment.

Maintained-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5-6, 17-18 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, **new matter**, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 25-28 are included in the rejection as being dependent upon claim 5.

The rejection was stated in the previous office action as it applied to previous Claims 5-6 and 17-18. In response to this rejection, applicants have amended Claims 5-6 and 17; and added Claims 25-28 and traverse the rejection as it applies to the newly amended claims.

Applicants noted claims 5 and 6 are amended to recite "and an optionally included covalently attached tag sequence..." in effort to further prosecution (see page 9, lines 6-8)

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants' argument is only applicable to Claim 6 because Claim 5 (Claims 17-18 and 25-28 dependent therefrom) has added amendment which recites "wherein the tag is optionally covalently attached..." (see 5th line of Claim 5) which makes the covalent attachment optional (i.e., encompassing covalent and non-covalent attachment; and inconsistent with the previous recited limitation of "included covalently attached tag sequence" in second line of Claim 5). The Examiner suggests to amend the Claim 5 similar to 5th line of Claim 6 to overcome instant rejection.

Withdrawn-Claim Rejections - 35 USC § 102

7. The previous rejection of Claims 5, 6, 9, 12, 17, 18, 20 and 22 under 35 U.S.C. 102(b) as being anticipated by Garfinkel et al. (US Patent 5,849,536, Dec. 15, 1998) as evidenced by Wu et al. (PNAS, 2006, Vol. 103, pages 18470-18474) is withdrawn by

virtue of applicants' amendment recite the intended "tag" and by virtue of the examiner's interpretation of the term "coupling agents" as explained herein.

It is noted that the instant claims recite "coupling agents" which can be "carbodiimide reagents and others", for example, in view of instant specification page 24, line 11-12. The term "others" described in the instant specification to describe what is encompassed by the "coupling agents" has been interpreted as a chemical entity for coupling said isolated substrate polypeptide; wherein many chemical entity for coupling a polypeptide is well known in the art; wherein said chemical entity is *not an amino acid sequence*, e.g., *peptide or polypeptide* (see definition of "coupling agent" in the attachment).

If applicants intend for the "coupling agents" to encompass peptides and/or polypeptides, applicant should so state and clarify the record as to what is encompassed by the term "coupling agents".

It is also noted that Claim 9 (Claims 17 and 29 dependent therefrom) is drawn to an isolated polypeptide having at least 90% or higher identity to (a) 1587-1668 of SEQ ID NO: 1 or (b) 1596-1668 of SEQ ID NO: 1; and the polypeptide has an ADAMTS-13 cleavage site at 1605th Tyr and 1606th Met; thus the polypeptide of Claim 9 does not read on the full length polypeptide taught by Garfinkel et al.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The previous rejection of Claims 11, 13, 14, 21 and 23-24 under 35 U.S.C. 102(b) as being anticipated by Garfinkel et al. (US Patent 5,849,536, Dec. 15, 1998) as evidenced by Wu et al. (PNAS, 2006, Vol. 103, pages 18470-18474) is maintained.

Applicants argue that the polypeptide of Garfinkel contains 2049 amino acids, which is much larger than the present invention and the interpretation of the present "optional" tag is unreasonable since there is no evidence that flanking residues of Garfinkel are even able to assume such function (see bottom of page 14 to top of page 15, Remarks filed on 6/4/2009).

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. However, the Claim 11 encompasses the polypeptide of claim 9, *further* having a tag sequence at the N-terminal and at the C-terminal wherein the recited tag sequence encompasses an amino acid sequence, *i.e.*, polypeptide. Thus, Claims 11, 13, 14, 21 and 23-24 read on the full length of polypeptide taught by Garfinkel et al. which having 100% identity compared to the polypeptide 1587-1668 or the polypeptide 1956-1668 of SEQ ID NO: 1 (see previously attached sequence alignment which is also attached below). Also, the interpretation of "a tag sequence" in Claim 11 is not unreasonable since the tag sequence is not limited in any way in terms of structural limitation; thus, encompasses any additional polypeptide that is attached to the claimed fragments (*i.e.*, the polypeptide 1587-1668 or the polypeptide 1956-1668 of SEQ ID NO: 1).

As noted previously, Garfinkel et al. teach the vWF GPIb binding domain polypeptide having residues disclosed as SEQ ID NO: 2 which comprises polypeptide 100% identical to instant polypeptide residues 1587-1668 (or 1596-1668) of SEQ ID NO: 1 (see Sequence Alignment in the attachment); wherein the polypeptide SEQ ID NO: 2 is expressed by pVWF-VCL according to the Fig. 13 description. The Example 4 in §19, lines 40-41, teaches isolation of the polypeptide encoded by pVWF-VCL by "improved methods a purer and more active polypeptide is produced"; thus meeting the limitation of "an isolated" in claims. The extra amino acids of Garfinkel et al. outside the 1587-1668 (or 1596-1668) of instant SEQ ID NO: 1 at the N-terminal and the C-terminal meets the limitation of having a tag sequence attached at the N-terminal and C-terminal; and the polypeptide of Garfinkel et al. meets the limitations of Claims 11, 14, 21 and 23-24. It is noted that the recitation of "for *in vitro* testing..." in claims 21 and 23-24 is an intended use limitation of the kit and has been accorded no patentable weight. The polypeptide of Garfinkel et al. has Cys at position 4 (see § 43-44) which can be used to attach to a maleimide bound resin which forms covalent bond with Cys; thus, meeting the limitation of Claim 13; wherein the recitation of "for immobilization on a solid phase is an intended use and does not necessarily contribute to the structure of claimed polypeptide. The polypeptide of Garfinkel et al. was further purified by ion exchange chromatography (see §, line54-55), which involves immobilization of protein on the ion exchange column; thus, meeting the limitation of Claim 14. The polypeptide of Garfinkel et al. was lyophilized (see §21, lines 37-44) and container holding the lyophilized polypeptide meets the limitation of a kit, thus, meeting the limitations of Claims 21, 23-

24, for an intended use of in vitro testing as shown by the biological testing shown in Example 5 in the §22 for ADAMTS-13 since the polypeptide comprises the cleavage site for ADAMTS-13 (i.e., Tyr1605-Met1606) and other residues such as 10 amino acids before and 63 amino acids after the scissile bond, which "is necessary for recognition and cleavage by ADAMTS-13" (see top right column, page 18470 of Wu et al.)

Conclusion

9. Claims ~~5-6, 9, 11-14, 17-18 and 20-29~~ are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Deleted: 9, 11-14, 17, 20-24 and 29

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656

/David J. Steadman/
Primary Examiner, Art Unit 1656

Art Unit: 1656

RESULT 1
 US-08-347-594A-2
 : Sequence Z, Application US/08347594A
 : Patent No. 5849536
 : GENERAL INFORMATION:
 : APPLICANT: Garfinkel, Leonard
 : APPLICANT: Richter, Tamar
 : TITLE OF INVENTION: CLONING AND PRODUCTION OF HUMAN VON
 : TITLE OF INVENTION: WILLEBRAND FACTOR GPIb BINDING DOMAIN POLYPEPTIDES AND
 : TITLE OF INVENTION: METHODS OF USING SAME
 : NUMBER OF SEQUENCES: 4
 : CORRESPONDENCE ADDRESS:
 : ADDRESSEE: John P. White
 : STREET: 1185 Avenue of the Americas
 : CITY: New York
 : STATE: New York
 : COUNTRY: USA
 : ZIP: 10036
 : COMPUTER READABLE FORM:
 : MEDIUM TYPE: Floppy disk
 : COMPUTER: IBM PC compatible
 : OPERATING SYSTEM: PC-DOS/MS-DOS
 : SOFTWARE: PatentIn Release #1.0, Version #1.25
 : CURRENT APPLICATION DATA:
 : APPLICATION NUMBER: US/08/347,594A
 : FILING DATE: No. 5849536ember 30, 1994
 : CLASSIFICATION: 435
 : ATTORNEY/AGENT INFORMATION:
 : NAME: White, John P.
 : REGISTRATION NUMBER: 28,678
 : REFERENCE/DOCKET NUMBER: 36537-B2
 : TELECOMMUNICATION INFORMATION:
 : TELEPHONE: 212-278-0400
 : TELEFAX: 212-391-0525
 : TELEX:
 : INFORMATION FOR SEQ ID NO: 2:
 : SEQUENCE CHARACTERISTICS:
 : LENGTH: 2050 amino acids
 : TYPE: amino acid
 : TOPOLOGY: linear
 : MOLECULE TYPE: protein
 US-08-347-594A-2

Query Match 100.0%; Score 428; DB 1; Length 2050;
 Best Local Similarity 100.0%; Pred. No. 7.6e-44;
 Matches 82; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 DHSFLVSGQDREQAPNLVYMTGNPASDEIKRLPGDIQVVPVIGVGPNNANVOELERIGWPN 60
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Dd 824 DHSFLVSGQDREQAPNLVYMTGNPASDEIKRLPGDIQVVPVIGVGPNNANVOELERIGWPN 883
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Qy 61 APILIQDFETLPRAPDLVLQR 82
 ||||||||||||||||
 Dd 884 APILIQDFETLPRAPDLVLQR 905